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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,431	06/05/2001	Karl Kolter	51497	5147

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/873,431	**Applicant(s)** KOLTER ET AL.	
	Examiner Blessing M. Fubara	**Art Unit** 1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 June 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because:
a) with regards to applicant's argument that the rejection relied on impermissible hindsight using applicant's invention as a guide and that Ortega fails to teach or suggest all of the elements of the claimed invention, it is noted that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the prior art, Ortega, discloses granulating a specific drug, theophylline and because Ortega does not dry granulate the theophylline composition, the rejection was not made under 35 USC 102 and examiner agrees with applicant that Ortega does not teach all the limitations of the claim 1, hence the rejection was not anticipatory rejection but a rejection, where Ortega renders obvious the claimed invention as described in the rejections of 9/27/05 and 2/27/07. While Ortega wet granulates and the claims dry granulate, both wet and dry granulations are employed in the process of making tablets as evidenced by the teaching of the 18th edition of Remington's Pharmaceutical Sciences at pages 1641 and 1644. Applicant provided no showing as to why preparing a generic sustained oral dosage form by known processes is inventive over a prior art process that prepares specific formulation by granulation, albeit, by wet granulation; and applicant has not shown why dry granulating theophylline, which is known in the art is inventive over wet granulating theophylline, which is also known in the art is inventive over the prior art. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). b) with regards to applicant's argument on the order of mixing the theophylline, polyvinyl acetate and polyvinylpyrrolidone, it is noted that the selection of any order of mixing the ingredients is prima facie obvious in the absence of new or unexpected results. c) regarding the product by process claim 17 and the claims that depend therefrom and applicant's argument that Ortega fails to teach or suggest a formulated mixture of polyvinyl acetate and polyvinyl where the polyvinyl pyrrolidone is finely dispersed in the polyvinylacetate and Ortega's second step cannot be reasonably deemed to correspond to component (a) of applicant's dosage form, it is noted that claim 14 is drawn to a product comprising polyvinyl pyrrolidone, polyvinylacetate and east one active ingredient and how the composition is made carries no patentable weight because product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps; and "[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." The composition of Ortega was never deemed to be equivalent to the claimed composition because, the rejection is not one of anticipation but one in which the claims are rendered obvious, the broad molecular weight of polyvinyl pyrrolidone is characteristic of polyvinyl pyrrolidone and polyvinyl acetate such that the recited broad molecular weight would be obvious. d) regarding applicant's statement that the argument presented for claim 17 is applicable to claim 25, it is noted that the response above is also applicable to claim 25 and further that since claim 25 delays the release of at least one active agent by producing the composition of claim 17, it flows that because Ortega also makes such a composition, the release of theophylline would also be delayed; the tablet of Ortega is a sustained release tablet (Title), which is a form of delayed release dosage form.

e) The rejection under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

BP